

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

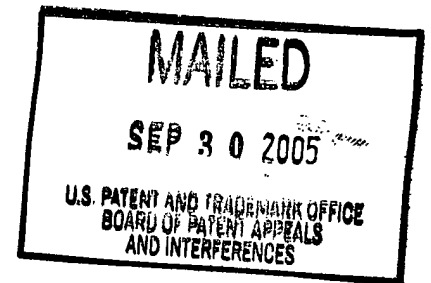
UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte MARVIN L. SCHILLING and
RICHARD D. FAFARD

Appeal No. 2005-2120
Application No. 09/964,120

ON BRIEF



Before MILLS, GRIMES, and GREEN, Administrative Patent Judges.

GREEN, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 42-50.¹ Claims 42 and 49 are the independent claims on appeal, and read as follows:

42. A method for the dehydration of Type II collagen containing cartilage in its natural form, which comprises,
(a) combining said cartilage with an antimicrobial agent and at least 15% by weight of the cartilage of an ionizing salt,

¹ Claim 51, which appears to be dependent on claim 49 (the claim states it is dependent on claim 39, but as claim 39 is not pending, we assume it should depend from claim 49), is also pending. As all rejections of claim 51 were withdrawn in the Examiner's Answer at page 3, claim 51 appears to be free of rejection.

- (b) heating the resulting mixture in particulate form at a temperature below which denaturization of the Type II collagen occurs until the water content is reduced to below 15 % by weight of the cartilage, and
- (c) recovering a product containing the collagen II-containing protein of the cartilage in its original form and having a salt content of at least 45% by weight of the cartilage.

49. The method of dehydrating chicken cartilage containing Type II collagen in its natural form which comprises

- (a) comminuting said cartilage,
- (b) soaking the resulting product in an aqueous solution of an antimicrobial agent, and blending such with potassium or sodium chloride in a concentration of at least 15 % by weight of the comminuted product,
- (c) dehydrating the resulting mixture in particulate form at temperatures below 110°F until the water content of the mixture is reduced to below 10 %, and recovering a product containing the Type II collagen of the chicken cartilage in its natural form and having a salt content of 45 to 60 % by weight of the cartilage.

The examiner relies upon the following references:

Moore	5,645,851	Jul. 8, 1997
Luck et al. (Luck)	4,250,139	Feb. 10, 1981
Steffan	4,404,033	Sep. 13, 1983
Ota	JP59025637 (translation)	Feb. 9, 1983

Claims 42-50 stand rejected under 35 U.S.C. § 103(a) as being obvious over the combination of Moore, Luck and Steffan. In addition, those claims stand rejected under 35 U.S.C. § 103(a) as being obvious over the combination of Moore and Ota. After careful review of the record and consideration of the issues before us, we reverse all of the rejections of record.

DISCUSSION

Claims 42-50 stand rejected under 35 U.S.C. § 103(a) as being obvious over the combination of Moore, Luck and Steffan.

Moore is cited for teaching obtaining Type II collagen from chicken cartilage, in which chicken is soaked in an aqueous solution containing 5.15% hypochlorite, the cartilage is removed and soaked in a 3% hydrogen peroxide, diced, and then dried at 110°F to remove over half the water content, wherein the dried product has improved shelf life, reduced volume and better handling. See Examiner's Answer, page 4. The examiner acknowledges that "Moore does not teach adding salt or [the] instant amount of salt." Id.

Luck is cited for teaching "a microwave sterilization of dry protein that retains the chemical, physical, and physiological properties of the proteinaceous materials by removing water substantially from the host material." Id. According to the rejection, "Luck [] teach[es] the protein is substantially dehydrated by placing the protein material in an aqueous solution in combination with salt, which is adventitiously present in the medium." Id. at 4-5.

Steffan is cited for teaching a method of making collagen fibers for surgical use, wherein sodium chloride is used in an amount of 5 to 15% for dehydration purposes. See id. at 5.

The rejection concludes:

It would have been obvious to one of ordinary skill in the art a [at, sic] the time the invention was made to combine the teachings of Moore and Luck [] and additionally utilize salt for dehydrating the cartilage. One would have been motivated to do so since Luck [] teach[es] a method of dehydrating protein material by placing the material in an aqueous medium containing salt, followed by lyophilization at instant temperatures to remove all of the water from the protein material and yet retain the physiological activity of the protein. Therefore, one would have been motivated to further add salt to Moore's method of dehydration to provide for

an additive effect of further facilitating and hastening the dehydration process. Moreover, it is prima facie obvious to combine two dehydrating techniques taught by the prior art for the same purpose, i.e. drying material containing protein and simultaneously retaining the activity of the material in order to form a third process for the very same purpose.

Further, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further look to Steffan and utilize the instant amount of salt in Moore's dehydration method. One would have been motivated to do so since Steffan teaches various salts are utilized to dehydrate collagen fibers, which is optimally utilized at the instant amount. Furthermore, the application of salt in the dehydration of collagen specifically versus cartilage containing collagen would still yield the same result since the function of salt as the drying agent would remain the same.

Id. at 5-6.

Appellants argue that the references do not provide motivation to arrive at the combination, and that the examiner has used hindsight to combine the references to arrive at the claimed invention. See Supplemental Appeal Brief, pages 6-7. We agree, and the rejection is reversed.

"A rejection based on section 103 clearly must rest on a factual basis, and these facts must be interpreted without hindsight reconstruction of the invention from the prior art. In making this evaluation, all facts must be considered. The Patent Office has the initial duty of supplying the factual basis for its rejection. It may not, because it may doubt that the invention is patentable, resort to speculation, unfounded assumptions or hindsight reconstruction to supply deficiencies in its factual basis. To the extent the Patent Office rulings are so supported, there is no basis for resolving doubts against their correctness. Likewise, we may not resolve doubts in favor of the Patent Office determination

when there are deficiencies in the record as to the necessary factual bases supporting its legal conclusion of obviousness.” In re Warner, 379 F.2d 1011, 1017, 154 USPQ 173, 178 (CCPA 1967), cert. Denied, 389 U.S. 1057 (1968) (emphasis in original).

Moore teaches a method of preparing Type II collagen containing cartilage for use as an oral supplement, wherein “it is essential that a sterilization procedure is employed which maintains the water insoluble structure of the Type II collagen in the animal tissue and also does not involve the denaturization of the Type II collagen in the animal tissue.” Col. 3, lines 20-24. In Example 12, the cartilage is dried in an oven at 110° F. until more than half its weight in water is lost. As acknowledged by the rejection, Moore fails to teach combining the Type II collagen containing cartilage with at least 15% by weight of an ionizing salt. The rejection relies on Luck and Steffan to remedy that deficiency.

Luck is drawn to the microwave sterilization of dry protein, in which the protein “can be one of a wide variety of classes of proteins, such as keratins, collagens, albumins, globulins, hormones, enzymes, or the like.” Col. 2, lines 12-15. Again, an object of Luck is to retain chemical, physical, and physiological properties of the protein. See abstract. In the method, the protein is dried by lyophilization, and then hit with a lethal dosage of microwave energy while the protein is maintained at substantially ambient conditions. See id. The reference teaches “[t]he protein is substantially dehydrated, either free of or in combination

with salts, which are or adventitiously [that is, not inherent, or coming from another source, see Reply Brief, page 2] present in the aqueous medium.” Luck, Col. 2, lines 32-37. Thus, while Luck teaches that an ionizing salt may be present, it does not provide any motivation to add a salt to the method of Moore, and furthermore, does not teach or suggest combining the protein with at least 15% by weight of an ionizing salt.

Steffan, however, is drawn to a method of manufacturing collagen fibers for surgical application. See Col. 1, lines 8-10. While as noted by the examiner, sodium chloride in an amount between 5 to 15% weight percent is used in the dehydration processes, see Col. 3, lines 32-34, before that, the collagen is subject to alkali treatment, acidification using hydrochloric acid to a pH less than 2, and mechanical treatment, see Col. 2, line 50-Col. 3, line 20, processes which are not designed to preserve the chemical, physical, and physiological properties of the protein. As such preservation of properties is an important object of the methods of Moore and Luck, the ordinary artisan would not look to Steffan for the addition of salt to the dehydration processes of those references to arrive at the claimed invention.

Claims 42-50 stand rejected under 35 U.S.C. § 103(a) as being obvious over the combination of Moore and Ota.

Moore is relied upon as above. The examiner acknowledges that “Moore does not specify the water content” and “does not teach adding salt.”

Examiner’s Answer, page 10.

Ota is cited for teaching a method of dehydrating scallops using salt. In the method, 7-15% salt is used to dehydrate the ligaments of the scallops, and, as noted by the rejection, "ligaments inherently contain collagen I." Id.

The rejection concludes:

It would have been obvious to one of ordinary skill in the art a [at, sic] the time the invention was made to combine the teachings of Moore and [Ota] and additionally utilize salt for dehydrating the cartilage. One would have been motivated to do so since [Ota] teaches the method of dehydrating ligaments with salt. Therefore, one would have been motivated to further add salt to Moore's method of dehydration to provide for an additive effect of further facilitating and hastening the dehydration process. Moreover, it is prima facie obvious to combine two dehydrating techniques taught by the prior art for the same purpose, i.e. drying material containing protein and simultaneously retaining the activity of the material, in order to form a third process for the very same purpose.

Further, one would expect similar results of utilizing salt to dehydrate Moore's cartilage since [Ota] dehydrates ligaments, which contains collagen albeit a different type of collagen than [than, sic] the one instantly claimed. The application of salt in the dehydration of Type I collagen versus Type II does not change the primary function of salt as a dehydrating agent. Salt will nonetheless act in a similar manner of removing water from the material to be dehydrated.

Id.

Appellants argue again that there is no motivation to combine the references to arrive at the claimed invention. We agree, and the rejection is reversed.

In this rejection, Ota is cited to remedy Moore's failure to teach combining the Type II containing cartilage with at least 15% by weight of an ionizing salt.

Ota teaches a method for salting scallops, in which 7-15% of salt is added to the thin-sliced scallop adductor muscles, which is then mixed with squid livers

that have been dehydrated also by the addition of 7-15% of salt. See Ota translation, page 2. The reference teaches that “[s]ince the decomposing activities of the proteins of squid livers can be utilized, a good flavor is produced when the proteins of the scallops become decomposed.” Id. at 3. Thus, as Ota is drawn to a method of decomposing the proteins of the scallops (the collagen source), and not designed to preserve the chemical, physical, and physiological properties of the protein, and as such preservation of properties is an important object of the method of Moore, the ordinary artisan would not look to Ota for the addition of salt to the dehydration process of Moore to arrive at the claimed invention.

CONCLUSION

Because the rejections of record failed to set forth a prima facie case of obviousness, they are reversed.

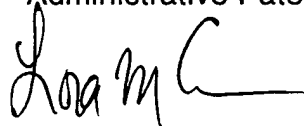
REVERSED



Demetra J. Mills
Administrative Patent Judge



Eric Grimes
Administrative Patent Judge



Lora M. Green
Administrative Patent Judge

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) BOARD OF PATENT
) APPEALS AND
) INTERFERENCES
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Bernd W. Sandt
900 Deerfield Ct.
Midland, MI 48640